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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,374	03/10/2004	Jeffrey O. Phillips	04242350	4467

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EXAMINER	
CHANG, CELIA C	
ART UNIT	PAPER NUMBER
1625	

NOTIFICATION DATE	DELIVERY MODE
11/10/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@mayerbrown.com

Office Action Summary	Application No.	Applicant(s)	
	10/797,374	PHILLIPS, JEFFREY O.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *237-289* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *237-289* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/17/08, 5/21/08, 10/3/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment and response filed by applicants dated July 31 , 2008 have been entered and considered carefully.

Claims 1-236 have been canceled. Claims 237-280 and new claims (291-299 renumbered) 281-289 are pending.

2. Claims 237-280 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement which is also applicable to newly added claims 281-289 is maintained for reason of record.

Applicants argued that the specification does not need to contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue experimentation. This is contrary to the description of the specification. The specification provided examples containing 12 mg disintegrant or 66 mg disintegrant while there was no description of what "range" would be for the instant invention. A table on page 8 of the response was submitted. No "description" as to what was the disintegrant, how much is in the claimed invention, how one having ordinary skill finds guidance. The same 12 mg of disintegrant gives various percentage of content in the total weight. By this presentation, it is even more confusing as to what is the scope intended for the claims, by mg? by %? By weight range? By % range? Without explicit "description" no support for the ambiguous scope of the claims can be found. While the incorporation of distintegrant is conventional modification in the pharmaceutical composition art and can be derived by one having ordinary skill, the specific range finds no antecedent basis as to be considered being applicants' invention. Applicants provided mere argument without pointing to where does antecedent basis for such a range described nor what was "known" conventionally in i.e effervescent art, in the chewing tablet art etc.

Further more, it was explained previously that the specification provided a composition comprising examples I.A-I.G3 specific composition and the description that such compositions would be useful to provide a blood concentration measurements as described on page 19 bout 0.1

μg/ml within about 15 minutes after administration of the composition. Such results can support the operability of these exemplified compositions wherein the buffering agent is sodium bicarbonate. There is no evidence in the record that a composition meeting the ratio requirement without using bicarbonate as the buffering agent or meeting the range requirement of the currently amended scope . Please note, the buffering agents as described in the specification (pages 115-117) have different pH, ionic strength, buffering capacity, there is no evidence that all such broad range of basic compounds can form buffer. There is no description or operability supporting that the wide varieties of basic agent generically encompassed by the terms would all function in analogous manner in providing serum absorption or omeprazole stabilizing effect with the bicarbonates. Especially, the scope of "oral" composition includes effervescent tablets or mixture for which quantities of bicarbonate and other acid/base or buffer . needs to be adjusted if strict pH range must be maintained. This complex preparation was disclosed on pages 44-45. Therefore, this is further evidence that the claims "oral composition" including effervescent preparation, the claimed buffering range is inoperable.

There is no range or guidelines as to what is the desired ratio of disintegrant in the instant invention. Applicants' presentation that 12 mg of croscamellose sodium was found in examples LB2, LC2, LD2, IF2 and IG2 do not provide any "range" of *disintegrant* of the claims because, it is clearly disclosed in the specification on page 42 that the disintegrants includes other material such as crospovidone, sodium starch glycolate and no relationship between the 12 mg croscamellose sodium can be extrapolated to ranges of all disintegrant material with completely different property, molecular weight and efficacy. Therefore, the instantly amended ranges are considered new matter and the rejection is maintained.

3. The rejection of claims 237-280 under 35 U.S.C. 102(f) or (g) as being anticipated by Hall et al. US2005/0037070 or Olmstead et al. US 2005/0266071 is maintained for reason of record.

To the extend that the inventive concept containing a particular composition comprising omeprazole, bicarbonate buffer and distintegrant with an explicit range, it was explained supra that antecedent basis for such concept was not found. Therefore, claim 1 of Olmstead et al. '071

which reads on the instant newly amended claim 237-280 presentation dated Oct. 31, 2007, is considered prior art under 35 USC 102(g).

To the extend that the inventive concept containing particular amounts of omeprazole, bicarbonate and sodium croscarmellose i.e. examples I.A-I.G3 as delineated on page 8 of the remark filed Oct. 31, 2007, the two references disclosed specific compositions i.e. species that anticipated the broad claims while the species of the instant application did not contain the two species of the references (see Hall et al. '070 p.21, examples 4 and 5; see Olmstead et al. '071, p.22 table 2.A.1 and 2.A.2). Since species anticipates the genus, were applicants argued that the ranges finds antecedent basis thus supports the generic claims, the 102(f) and (g) issues must be resolved. Please note that the species of the two references always anti-dates the instant application since no such composition was disclosed, nor was any range concept finds description in the specification.

Applicants argued that the instant application has priority dates traced back to 1996. Please note that in the 60/009608 application, the disintegrant croscarmellose sodium (supporting the 12 and 66 mg of applicants' range) was not found.

4. The rejection of claims 237-280 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,489,364 in view of Jung et al. CA 128:261816 is now applicable to claims 281-289 and maintained for reason of record.. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to prima facie obvious inclusion of the croscarmellose sodium which has been well recognized in the art to be an conventional disintegrant (see US 4,639,458; 4,681,765; 4,904,477; 4,910,022; 5,256,699; 5,370,878; 5,861,172 etc. *references will not be listed on 892* i.e. per ponderous of evidence), and it is also known to be operable with omeprazole (see Choi et al.).

Claims 237-280 are rejected as being unpatentable over claims 18-56 of US 6,489,364 or claims 1-51 of US 6,699,885 or the claims are provisionally rejected over the copending claims 24-25, 32-36, 77-88, 90-100, 103-110 of SN 10/641,732, on the ground of nonstatutory obviousness-type double patenting. Although the conflicting claims are not identical, they are

not patentably distinct from each other because the instant claims are drawn to material being used in the issued claims or copending claims with prima facie obvious inclusion of a conventional disintegrant. The prima facie obvious material and method of using such prima facie obvious material should be bind together to prevent unreasonable multiple harassment based on the decision of In re Ochai. Please note that no restriction between the material and method of using the identical material was made. Therefore were the claims presented in a single application, they would be joined in issuance.

No acceptable terminal disclaimer was filed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Oct. 29, 2008

/Celia Chang/
Primary Examiner
Art Unit 1625